

REMARKS

Claims 21, 56, 58, 60, 62, 63, 65, 67, and 72 are pending in the application. Claims 21, 56, 58, 60, 62, 63, 65, 67, and 72 are rejected. Claims 54, 55, and 68-70 are canceled. Claims 21, 56, 63, 65, and 67 are amended herein. Claims 21, 56, 58, 60, 62, 63, 65, 67, and 72 remain for consideration.

In this case, the Examiner has issued five office actions since the first final action issued on 9-22-06. Of the currently rejected claims, claims 21, 56, 62 and 63 were held to be allowable in each of these office actions, including the 9-22-06 final office action. Claims 58 and 60 were held to be allowable in the office actions of 1-30-07, 07-16-07, held not to be allowable in the office action of 11-02-07, again held to be allowable in the office action of 5-15-08, and now stand currently rejected. Claims 65 and 72 were held to be allowable in the office action of 9-22-06 but were held not to be allowable in the office actions of 1-30-07, 07-16-07, were again held to be allowable in the office actions of 11-02-07 and 5-15-08, but are currently rejected. Claim 67 was held to be allowable in the office actions of 11-02-07 and 5-15-08, but is currently rejected.

In Applicant's responses filed 9-17-09, 3-3-08 and 8-26-08, Applicant made no amendments other than to overcome claim objections in accordance with the Examiner's instructions or to cancel rejected claims. Nevertheless, Applicant is now facing a rejection of claim 62 over USPN 5,026,373 to Ray et al., despite claim 62 being held patentable in office actions citing Ray '373 on 1-30-07, 7-16-07, and 11-02-07. Additionally, the Examiner is rejecting the remaining claims over a *newly* cited reference cited in the seventh office action in the pending case.

Applicant directs the Examiner to MPEP 904.03, which states, "It is a prerequisite to a speedy and just determination of the issues involved in the examination of an application that careful and comprehensive search . . . be made in preparing the first office action on the merits so that the second action on the merits can be made final or the application allowed with no further searching other than to update the original search." (MPEP Rev. 5, Aug. 2006, page 900-51)

*Claim Rejections - 35 USC 112*

The Examiner rejects claims 21, 56, 63, 65, and 67 as being indefinite because the Examiner does not understand the limitation "wherein said port is defined by said end cap." The Examiner does not understand the meaning of the wherein clause. The Examiner suggests that Applicant should substitute the phrase "defined by" with the phrase "located in."

Claims 21, 56, 63 65 and 67 are amended in accordance the Examiner's requirement.

*Claim Rejections - 35 USC §102(b)*

The Examiner rejected claim 62 as being anticipated by US Patent No. 5,026,373 to Ray et al. The Examiner stated:

Ray et al discloses an interbody spine fusion comprising a body (10) defining an outside surface, a carrier receiving area (hollow section of element 10), implanting the bone implantable device adjacent a target bone structure applying an un-doped sponge material (see col. 10, lines 9-12, the bone), a port (opening at extremities of element 10), and a pathway (13).

Claim 62 is amended for antecedent basis purposes. The following claim element of claim 62 is not anticipated by Ray et al.:

an un-doped, sponge material loaded in said carrier receiving area;

The Examiner refers to language found in column 10, lines 9-12 of Ray et al., which states, "After removing the wrench, the cage is packed with bone chips or other bone inducing substance, and the second end cap is applied to hold the bone chips securely in place." The cited passage of Ray et al. fails to anticipate the above-listed claim language for two reasons. First, the term, "bone chips" does not meet the claim limitation, "sponge material." Second, Ray et al.'s language, "bone chips or other bone inducing substance" does not meet the claim limitation, "un-doped." An un-doped sponge material onto which is delivered "a biologically active substance" per the claim, is not a bone inducing substance. Ray et al.'s teachings regarding bone inducing substances, therefore, do not anticipate the claim language, "un-doped sponge material." Allowance of claim 62 over Ray et al. is respectfully requested.

*Claim Rejections - 35 USC 102(e)*

The Examiner rejected claims 21, 56, 58, 60, 62, 63, 65, and 67 as being anticipated by US Patent No. 6,605,089 to Michelson. The Examiner states:

Michelson discloses an interbody spine fusion comprising a body (130) defining an outside surface, a carrier receiving area (36), implanting the bone implantable device adjacent a target bone structure applying an un-doped carrier material, a port (opening closed by cap element 125), a pathway (142), an end cap (125) and a plug (120 & 122). The port is defined by the end cap. The plug is penetrated by a delivery device (196) (it delivers electric current).

Regarding claim 63, the plug is capable of being penetrated by a syringe. Claim 63 is a functional language claim.

At least the following claim elements of Claim 21 are not anticipated by Michelson '089:

an un-doped carrier material loaded in said carrier receiving area;  
a port that communicates said outside surface with said carrier receiving area for facilitating delivery of a biologically active substance onto said un-doped carrier material;

wherein said port is defined by said end cap; and further comprising: a plug in said port adapted to be penetrated by a delivery device.

Each of these claim elements will be addressed separately, below. Additionally, similar elements in rejected claims 56, 58, 60, 62, 63, 65, and 67 are also presented and identified. The rejections associated with like claim elements in various claims are addressed together.

- (i) *an un-doped carrier material loaded in said carrier receiving area; (claims 21, 56)*  
*an un-doped collagen carrier material loaded in said carrier receiving area; (claims 58, 60)*  
*an un-doped, sponge material loaded in said carrier receiving area; (claim 62)*

Michelson '089 teaches that, "housing 130 is similar to the housing 30 described above..." (col. 10, lines 65 – 67) and that, "The hollow chamber 36 can be filled with and may hold any natural or artificial osteoconductive, osteoinductive, osteogenic, or other *fusion enhancing material*" (col. 8, lines 49 – 52; emphasis added). Michelson '089 teaches no un-doped carrier material, or a carrier material of any kind. An "un-doped carrier material" onto which a biologically active substance is to be delivered in accordance with the claims, cannot be construed as a fusion enhancing material. Allowance of claims 21, 56, 58, 60, and 62 over Michelson '089 is respectfully requested.

- (ii) *a port that communicates said outside surface with said carrier receiving area for facilitating delivery of a biologically active substance onto said un-doped carrier material; (claims 21, 56, 58, 60)*  
*wherein said/a port is located in said end cap; (claims 21, 56, 58, 60, 63, 65, 67)*

The Examiner states that Michelson '089 teaches, "a port (opening closed by cap element 125)". With reference to Michelson '089, Fig. 4, proximal end 140 receives threaded cap element 125. In other words, the "port", as defined by the Examiner, is the proximal open end 140 of cage body 130. However, Applicant's claim 21 requires the port to be "located in said end cap". This language is contradictory to the Examiner's definition of "port". The teachings of Michelson '809 fail to teach a, "port.... for facilitating delivery of a biologically active substance onto said undoped carrier material... *wherein said port is located in said end cap*". Allowance of claims 21, 56, 58, 60, 63, 65 and 67 over Michelson '089 is respectfully requested.

*(iii) a plug in said port adapted to be penetrated by a delivery device. (claim 21)*

*a plug in said port adapted to be penetrated by a syringe; (claims 56 58, 60, 63)*

*a plug in said port, said plug adapted to be patentable by a syringe. (claim 65, 67)*

The Examiner states that Michelson '809's numerals 120 & 122 refer to a plug. The Examiner further states that, "The port is defined by the end cap. The plug is penetrated by a delivery device (196) (it delivers electric current)."

Michelson labels 120 as a "screw" and 122 as a "conductive inner core". The "port", as defined by the Examiner, i.e., "opening closed by cap element 125" is not located in the end cap (see, arguments in section *(ii)*, immediately above). Neither screw 120, nor conductive inner core 122 are penetrated by head portion 196 i.e., "the active anode" (see, col. 11, line 9). Instead,

“conductive inner core 122, and an insulated stem portion 123 having a recess 126 [*are provided*] for coupling to the head potion 196 (the active anode)” (emphasis added; col. 11, lines 7-9). Michelson ‘089 has no teachings with regards to a plug being penetrated by a delivery device. To the extent that an “active anode” could be construed as the claimed delivery device, the active anode, a.k.a. head portion 196, is coupled to insulated stem portion 123 rather than penetrating anything (see, e.g., col. 11, lines 8 – 11). Allowance of claims 21, 56, 58, 60, 63 and 65 over Michelson ‘089 is respectfully requested.

Note that claims 65 and 67 have been amended to re-order claim elements for antecedent basis purposes.

***Claim Rejections - 35 USC 103(a)***

The Examiner rejected claim 72 as being unpatentable over US Patent No. 6,605,089 to Michelson. The Examiner stated:

Michelson discloses the invention substantially as claimed. However, Michelson does not disclose a syringe as a delivery device.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the step of inserting biological active substances of the Michelson reference because Applicant has not disclosed that by having the above mentioned substance provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with Michelson reference because it would perform equally as well.

Therefore, it would have been an obvious matter of design choice to modify the Michelson reference to obtain the invention as specified in claim 72.

As explained above, Michelson does not teach the invention substantially as claimed. Instead, Michelson fails to teach, for example, at least 4 of 8 claim elements in claim 21. Furthermore, Applicant respectfully disagrees with the Examiner's assertion that it would have

been an obvious matter of design choice to modify Michelson's reference to obtain Applicant's invention as specified in claim 72. Michelson teaches a cap element 125, that threadably receives insulating stem portion 123, which, in turn receives conductive inner core 122 of screw 120 (see., Fig. 4), "for coupling" (col. 11, line 8, 9) with "head portion 196 (the active anode)" (col. 11, line 9). Nowhere does Michelson teach or suggest that anything penetrates the above structure. In particular, nowhere does Michelson teach that a delivery device penetrates the above structure.

Furthermore, one skilled in the art would never consider it to be matter of design choice to modify a conductive screw assembly that, "conducts positive charge from the head portion 196 to the conductive screw head 121" (col. 11, lines 10, 11) to obtain a plug adapted to be penetrated by a delivery device wherein said delivery device is a syringe. The two devices are structurally dissimilar and function in completely different ways. Allowance of 72 over Michelson '089 is respectfully requested.

### *Conclusion*

For these reasons, and in view of the above amendments, this application is now considered to be in condition for allowance and such action is earnestly solicited. However, should there remain unresolved issues that require adverse action, it is respectfully requested that the Examiner telephone James F. Lea III, Applicants' Attorney at 918/599-0621 so that such issues may be resolved as expeditiously as possible.

This paper is intended to constitute a complete response to the outstanding Office Action. Please contact the undersigned if it appears that a portion of this response is missing or if there remain any additional matters to resolve. If the Examiner feels that processing of the application

can be expedited in any respect by a personal conference, please consider this an invitation to contact the undersigned by phone.

Respectfully Submitted,

June 4, 2009  
Date

  
James F. Lea III, Reg. No. 41143

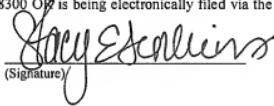
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